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(71) Applicant(s)

**Bespak Plc**  
(Incorporated in the United Kingdom)  
Bergen Way, North Lynn Industrial Estate,  
KING'S LYNN, Norfolk, PE30 2JJ, United Kingdom

(72) Inventor(s)

**Geoff Brace**

(74) Agent and/or Address for Service

**Boulton Wade Tennant**  
27 Fumival Street, LONDON, EC4A 1PQ,  
United Kingdom

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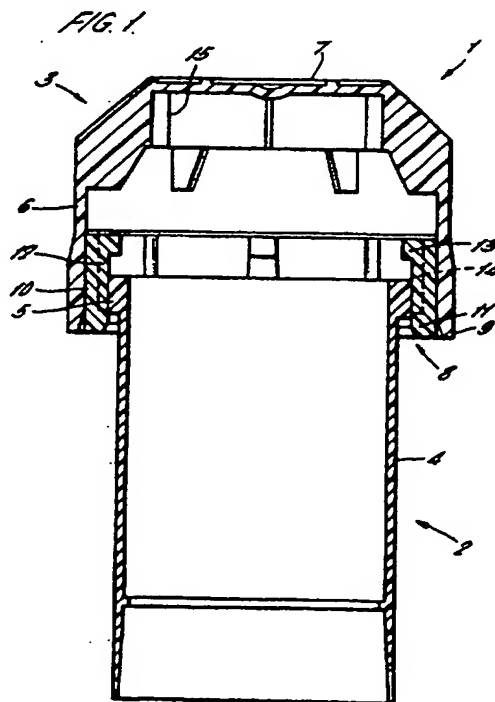
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**A5T TBE**

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**GB 2061116 A WO 93/09830 A1**

(58) Field of Search  
UK CL (Edition O ) **A5T TBE**  
INT CL<sup>6</sup> **A61M 15/00**  
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(54) Abstract Title  
**Inhalation apparatus**

(57) The apparatus comprises a housing (2) and an end cap (3) axially slidable relative to the housing. The housing comprises a portion adapted to receive a pressurised dispensing container and connected to a mouthpiece, and duct means communicating with the container receiving portion for conveyance of product towards the mouthpiece. The end cap comprises a socket for engaging the pressurised dispensing container and has a collar (10) with an inwardly directed rim (11). The housing includes an outwardly directed flange (5) which fits within said rim. The end cap is movable between a first position in which said rim and flange have an axial overlap and there is no or a minimal flow of air through the housing and a second position in which there is a maximum flow of air, the air flow being created by a user applying suction to the mouthpiece.



GB 2 323 041 A

INHALATION APPARATUS

5           This invention relates to an inhalation apparatus  
for dispensing substances for inhalation and, in  
particular, but not exclusively, for dispensing  
medicinal products in aerosol form from a pressurised  
dispensing container.

10           It is known to provide a sensor in an inhalation  
apparatus to detect inhalation by the user in order to  
synchronise with inhalation the release into the  
inhaled air flow of the substance to be inhaled. It  
15   is, for example, important in the administration of  
aerosol products for the relief of asthma that the  
timing of the dispensing operation should be carefully  
controlled to ensure maximum deposition of substance  
in the user's lungs.

20           It is known from GB 2266466 to provide an  
electrically operated dispensing means responsive to a  
signal generated by a sensor which is responsive to a  
flow of air through the passageway. The disadvantage  
25   of this solution is that the apparatus is expensive.

          An object of the present invention is to provide  
dispensing means in which mechanical means are used to  
co-ordinate the release of the substance with the  
30   inhalation.

          The present invention therefore provides an  
inhalation apparatus for dispensing a product  
comprising a housing and an end cap axially slidable  
35   relative to the housing, said housing comprising a

portion adapted to receive a pressurised dispensing container and being connected to a mouthpiece, and duct means communicating with the container receiving portion for conveyance of product towards the mouthpiece; said end cap comprising a portion for engaging the pressurised dispensing container; one of said end cap and housing comprising an inwardly directed rim; the other of said end cap and housing including an outwardly directed flange which fits within said rim; said end cap being movable between a first position in which said rim and flange have an axial overlap and there is no or a minimal flow of air through said housing and a second position in which there is a maximum flow of air, the air flow being created by a user applying suction to the mouthpiece.

An advantage of the present invention is that the dispensation of the medicament is synchronised with inhalation of the user using an inexpensive inhalation apparatus.

Preferably said end cap is movable to a third position, the movement of the end cap between the second and third positions providing means for the dispensing of the product into the maximum air flow and for delaying the discharge of the product until the maximum air flow has been established.

Preferably the end cap comprises the inwardly directed rim and the housing comprises the outwardly directed flange.

Alternatively the housing comprises the inwardly directed rim and the end cap comprises the outwardly directed flange.

Preferably the end cap comprises a collar comprising the inwardly directed rim and a plurality of axial ribs on an internal surface of the collar, said rim and ribs, with the end cap in the first position, forming a close fit with the outwardly directed flange of the housing so that there is no or a minimum air flow through the housing, an end of the axial ribs furthest from the rim comprising position stops for contacting the rim when the end cap is in the third position to prevent axial movement of the rim beyond the stops; the collar further comprising circumferential recesses between the ribs such that with the end cap in the second or third positions, the maximum air flow can pass through the circumferential recesses between the housing and the collar when a user applies suction to the mouthpiece.

Alternatively the housing comprises a collar comprising the inwardly directed rim and a plurality of axial ribs on an internal surface of the collar, said rim and ribs, with the end cap in the first position, forming a close fit with the outwardly directed flange of the end cap so that there is no or a minimum air flow through the housing, an end of the axial ribs furthest from the rim comprising position stops for contacting the rim when the end cap is in the third position to prevent axial movement of the rim beyond the stops; the collar further comprising circumferential recesses between the ribs such that with the end cap in the second or third positions, the maximum air flow can pass through the circumferential recesses between the housing and the collar when a user applies suction to the mouthpiece.

Preferably the minimum air flow is provided by a

bleed hole in the housing.

Alternatively the minimum air flow is provided by a bleed hole in the end cap.

5

An advantage of providing a bleed hole is that a minimum air flow is provided when suction is applied to the mouthpiece even when the apparatus is in the rest state with the rim and flange having an axial overlap. This prevents the user of the inhalation apparatus panicking by being unable to inhale a quantity of air.

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Preferably the ratio of the maximum volume flow rate of air to the minimum volume flow rate of air lies in the range 8 to 12.

15

Preferably the ratio of the maximum volume flow rate of air to the minimum volume flow rate of air lies is approximately 10.

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Preferably the end cap is biased in use into the first position by means of the pressurised dispensing container.

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An advantage of the present invention is that the apparatus does not require a separate spring component in order to operate. This helps to reduce the manufacturing and assembly costs of the apparatus.

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Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings of which:-

35

Figure 1 is a sectional view of a part of a first

embodiment of the present invention;

Figure 2 is a perspective view of a part of the first embodiment of the present invention;

5 Figure 3a is a sectional view of a part of the first embodiment of the present invention in a first position;

Figure 3b is a sectional view of a part of the first embodiment of the present invention in a second position;

10 Figure 3c is a sectional view of a part of the first embodiment of the present invention in a third position;

Figure 4 is an exploded sectional view of a second embodiment of the present invention;

15 Figure 5 is a perspective view of a part of the second embodiment of the present invention;

Figure 6 is a sectional view of a second embodiment of the present invention.

20 Referring to Figure 1, a first embodiment of the apparatus 1 comprises a housing 2 and an end cap 3. The housing 2 comprises a generally cylindrical portion 4 open at both ends. The cylindrical portion 4 has an outwardly directed circumferential flange 5 of  
25 enlarged external diameter at one end. The apparatus 1 further includes a mouthpiece incorporating a stem block for receiving in use a valve stem of a pressurised dispensing container. The mouthpiece is coupled to the housing 2 at the end of the housing 2  
30 remote from the circumferential flange 5 by means of a push fit. Preferably the mouthpiece and the housing 2 are manufactured as a single component, for example, by means of a plastic moulding.

35 The end cap 3 comprises a generally cylindrical

portion 6 closed at one end to form an end face 7.  
The cylindrical portion 6 of the end cap 3 comprises  
an open end 8 having a flared circumferential skirt 9.  
A collar 10, as shown in Figure 2, is received in the  
5 open end 8 of the end cap 3 and is held in the  
cylindrical portion 6 by means of an interference fit  
between the external diameter of the collar 10 and the  
internal diameter of the cylindrical portion 6 of the  
end cap 3.

10

The collar 10 comprises an internal rim 11 and  
axial ribs 12, on the internal surface of the collar  
10, spaced around the circumference of the collar 10.  
Between the axial ribs 12 are positioned  
15 circumferential recesses 14. The external diameter of  
the circumferential flange 5 of the housing 2 is  
slidably engagable with the internal surface of the  
rim 11 and ribs 12 of the collar 10. The external  
diameter of the circumferential flange 5 forms a close  
20 fit with the internal diameter of both the rim 11 and  
the ribs 14 of the collar 10 sufficient to limit  
substantially and possibly prevent the flow of air  
between the rim 11 and circumferential flange 5 when  
the rim 11 and circumferential flange are axially  
25 aligned but which is not sufficient to prevent axial  
movement of the circumferential flange 5 relative to  
the collar 10. Position stops 13 are provided on each  
axial rib 14 on an end of the collar 10 nearest the  
end face 7 of the end cap 3 to position the collar 10  
30 on first actuation of the apparatus.

Before first use the collar 10 is positioned over  
the housing 2 with the position stops 13 resting on  
the distal end of the circumferential flange 5. The  
35 end cap 3 is placed over the collar 10. The collar 10

is preferably designed not to be removed from the end cap 3 throughout the working lifetime of the apparatus 1. The pressurised dispensing container is inserted, with the valve stem of the container downwards (as viewed in Figure 1), into the housing 2. The base of the pressurised dispensing container is received within a socket 15 of the end cap 3 and held in position by means of an interference fit between the socket 15 and container. The apparatus 1 is fully actuated by depressing the end cap 3. This movement forces the collar 10 axially along the end cap 3 by means of the flange 5 of the housing 2 being in contact with the position stops 13 of the collar 10. The collar 10 comes to its rest position where preferably it remains throughout the working life of the inhaler. The rest position of the collar 10 is such that in future operation of the inhaler the flange 5 comes into contact with the position stops 13 at the same time as the valve stem of the dispensing container is fully depressed. Thus the axial movement of the collar 10 relative to the housing 2 is limited by the stroke length of the valve stem of the dispensing container. In the assembled position there exists a gap between the internal surface of the housing 2 and the external surface of the dispensing container which may determine the maximum opening and hence the maximum volume air flow rate through the housing.

A mouthpiece comprising a stem block (not shown but of known type) is removably coupled to the end of the housing 2 furthestmost from the circumferential flange 5. The valve stem of the pressurised dispensing container is engagable within the stem block of the mouthpiece. Thus when the apparatus 1 is



assembled the end cap 3 is axially slidable relative to the housing 2 and mouthpiece; the axial movement of the end cap 3 being limited solely by the stroke length of the valve of the dispensing container. The axial movement is limited at one extreme by the rest position of the dispensing can and at the other extreme by the position of the dispensing container with the valve stem in the fully depressed state.

In a first, rest position of the apparatus, as shown in Figure 3a, the length of the housing 2 relative to the dispensing container is such that the circumferential flange 5 is at least partially aligned with the raised rim 11 of the collar 10. The fit between the circumferential flange 5 and rim 11 largely prevents the passage of air between the raised rim 11 and circumferential flange 5. Thus, when a user of the inhalation apparatus applies suction to the mouthpiece, no substantial air flow between the rim 11 and circumferential flange 5 is produced. It is to be desired that in the first position with the circumferential flange 5 and rim 11 in alignment there is a minimum volume flow rate of air through the inhaler into the user's mouth when suction is applied to the mouthpiece 7. This minimum flow of air helps to prevent any sense of panic which may occur if the user of the inhaler was not able to inhale a quantity of air. Such a minimum volume flow rate of air may be produced by incorporating a bleed hole in the collar 10. Alternatively, the minimum volume flow rate of air may be ensured by designing the circumferential flange 5 and rim 11 interface to have a minimum leakage of air whilst in the first position or incorporating a bleed hole in another portion of the housing or end cap 2, 3. Thus, the inhaler has a

minimum volume flow rate of air through the inhaler with the housing 2 in a first position corresponding to non-actuation of the apparatus 1. The ratio of the maximum to minimum volume flow rates may be varied greatly, and may be easily adjusted by altering the size of the bleed hole and/or the nature of the sealing contact of the rim 11 with the circumferential flange 5. Preferably, the ratio of the maximum to minimum volume flow rates of air lies in the range of 8 to 12 and preferably the ratio of maximum to minimum volume flow rates of air is approximately 10.

To actuate the apparatus, the user of the inhaler depresses the end face 7 of the end cap 3. This causes the valve stem of the dispensing container to start to slide and, at the same time, the circumferential flange 5 to slide relative to the collar 10 from a first to a second position, as shown in Figure 3b, bringing the circumferential flange 5 into axial alignment with the circumferential recesses 14 of the collar 10. In this second position, an air flow path, shown by the arrows marked 'A' in Figures 3b and 3c, is created from a position external the inhalation apparatus 1 through the open end 8 of the end cap 3, through the circumferential recesses 14 and into the housing 2. The air then passes between the housing 2 and the dispensing container and into the mouthpiece. This air flow comprises a maximum volume flow rate through the apparatus 1. Continued depression of the end cap 3 moves the housing 2 to a third position, as shown in Figure 3c, where the circumferential flange 5 contacts the position stops 13, preventing further axial movement of the housing 2. The dispensing container discharges a dose of medicament into the air flow as the end cap 3 moves

from the second position to the third position.  
Alternatively the dispensing container discharges a  
dose simultaneously with the end cap 3 reaching the  
third position.

5

The reliable operation of inhalers, in terms of  
consistent timing of the discharge of product and full  
dispensation of each metered dose, has been found to  
be dependant to a certain extent on the variation in  
10 height of the body of the dispensing container, which  
has been found to vary by up to an amount of the same  
order as the stroke length of the valve stem.

The present invention overcomes this reliability  
15 problem due to the fact that when the apparatus is  
first assembled the collar 10 is placed in the end cap  
3 and the pressurised dispensing container and  
mouthpiece are coupled to the end cap 3 and the  
apparatus 1 is actuated by firmly squeezing together  
20 the end cap 3 and mouthpiece. This has the effect of  
moving the collar 10 axially within the end cap 3 to a  
point where the fully depressed state of the valve  
stem of the pressurised dispensing container  
corresponds to the third position of the end cap in  
25 which the flange 5 contacts the position stops 13 .  
The collar 10 is held fixed by the tight fit between  
the collar 10 and end cap 3 when the apparatus 1 is  
released, thus the apparatus 1 is 'set up' for the  
individual characteristics of the dispensing container  
30 inserted. The reliability of the apparatus 1 is  
further improved due to the fact that the minimum air  
flow is ensured even if the flange 5 and rim 11 only  
partially axially overlap. The length of the  
cylindrical portion 6 of the end cap 3 allows a degree  
35 of axial movement of the collar 10 relative to the

dispensing container during the initial 'setting up' of the apparatus 1. The length of the cylindrical portion 6 thus provides a tolerance of several millimetres for the accurate positioning of the collar 10 with the housing 2 in the first position.

The timing of the discharge of the container can be easily varied in relation to the start of the maximum air flow by altering the axial length of the collar 10 or circumferential recesses 14. In particular altering the axial length of the rim 11 and flange 5 will alter the degree of axial movement of the housing 2 that is required to move the rim 11 and flange 5 from the overlapping state to the non-overlapping state and hence from the minimum air flow position to the maximum air flow position.

A second embodiment of the present invention is shown in Figures 4 to 6. Features in common with the first embodiment have been designated with like reference numerals.

The apparatus 1 comprises a housing 2 and an end cap 3. The housing 2 comprises a generally cylindrical portion 4 open at both ends. The apparatus 1 further includes a mouthpiece 20 incorporating a stem block for receiving in use a valve stem of a pressurised dispensing container. The mouthpiece 20 is coupled to the housing 2 at the end of the housing 2 by means of a push fit. Preferably the mouthpiece 20 and the housing 2 are manufactured as a single component, for example, by means of a plastic moulding.

The end cap 3 comprises a generally cylindrical

portion 6 closed at one end to form an end face 7.  
The cylindrical portion 6 of the end cap 3 comprises  
an open end 8 having an outwardly directed  
circumferential flange 5. A collar 10, as shown in  
5 Figure 6, is received in the open end of the housing 2  
and is held in the cylindrical portion 4 by means of  
an interference fit between the external diameter of  
the collar 10 and the internal diameter of the  
cylindrical portion 4 of the housing 2.

10

The collar 10 as shown in Figure 5 comprises an  
internal rim 11 and axial ribs 12, on the internal  
surface of the collar 10, spaced around the  
circumference of the collar 10. Between the axial  
15 ribs 12 are positioned circumferential recesses 14.  
The external diameter of the circumferential flange 5  
of the housing 2 is slidably engagable with the  
internal surface of the rim 11 and ribs 12 of the  
collar 10. The external diameter of the  
20 circumferential flange 5 forms a close fit with the  
internal diameter of both the rim 11 and the ribs 14  
of the collar 10 sufficient to limit substantially and  
possibly prevent the flow of air between the rim 11  
and circumferential flange 5 when the rim 11 and  
25 circumferential flange 5 are axially aligned but which  
is not sufficient to prevent axial movement of the  
circumferential flange 5 relative to the collar 10.  
Position stops 13 are provided on each axial rib 14 on  
an end of the collar 10 nearest the mouthpiece 20 of  
30 the housing 2 to position the collar 10 on first  
actuation of the apparatus.

Before first use the collar 10 is placed in the  
housing 2 with the position stops 13 nearest the  
35 mouthpiece 20. The pressurised dispensing container is

inserted, with the valve stem of the container downwards (as viewed in Figure 6), into the housing 2 and through the collar 10. The end cap 3 is push fit over the base of the dispensing container such that  
5 the flange 5 is positioned within the collar 10. The collar 10 is preferably designed not to be removed from the housing 2 throughout the working lifetime of the apparatus 1. The apparatus 1 is fully actuated by depressing the end cap 3. This movement forces the  
10 collar 10 axially along the end cap 3 by means of the flange 5 of the end cap 3 being in contact with the position stops 13 of the collar 10. The collar 10 comes to its rest position where preferably it remains throughout the working life of the inhaler. The rest  
15 position of the collar 10 is such that in future operation of the inhaler the flange 5 comes into contact with the position stops 13 at the same time as the valve stem of the dispensing container is fully depressed. Thus the axial movement of the collar 10  
20 relative to the housing 2 is limited by the stroke length of the valve stem of the dispensing container. In the assembled position there exists a gap between the internal surface of the housing 2 and the external surface of the dispensing container which may  
25 determine the maximum opening and hence the maximum volume air flow rate through the housing.

Operation of the second embodiment of the present invention is similar to the first embodiment; movement  
30 of the end cap 3 between the first, second and third positions actuating the apparatus 1 and controlling the flow of air when a user applies suction to the mouthpiece 20.

35 All of the components of the apparatus 1 can be

plastics mouldings.

It will be appreciated that various modifications  
to the construction of the apparatus 1 may be made  
5 without departing from the scope of the invention.

**CLAIMS:-**

1. An inhalation apparatus for dispensing a product comprising a housing and an end cap axially slidable  
5 relative to the housing, said housing comprising a portion adapted to receive a pressurised dispensing container and being connected to a mouthpiece, and duct means communicating with the container receiving portion for conveyance of product towards the  
10 mouthpiece; said end cap comprising a portion for engaging the pressurised dispensing container; one of said end cap and housing comprising an inwardly directed rim; the other of said end cap and housing including an outwardly directed flange which fits  
15 within said rim; said end cap being movable between a first position in which said rim and flange have an axial overlap and there is no or a minimal flow of air through said housing and a second position in which there is a maximum flow of air, the air flow being  
20 created by a user applying suction to the mouthpiece.
2. An inhalation apparatus as claimed in claim 1 wherein said end cap is movable to a third position, the movement of the end cap between the second and  
25 third positions providing means for the dispensing of the product into the maximum air flow and for delaying the discharge of the product until the maximum air flow has been established.
- 30 3. An inhalation apparatus as claimed in claims 1 or 2 wherein the end cap comprises the inwardly directed rim and the housing comprises the outwardly directed flange.
- 35 4. An inhalation apparatus as claimed in claims 1 or



2 wherein the housing comprises the inwardly directed rim and the end cap comprises the outwardly directed flange.

5 5. An inhalation apparatus as claimed in claim 3, wherein the end cap comprises a collar comprising the inwardly directed rim and a plurality of axial ribs on an internal surface of the collar, said rim and ribs, with the end cap in the first position, forming a  
10 close fit with the outwardly directed flange of the housing so that there is no or a minimum air flow through the housing, an end of the axial ribs furthest from the rim comprising position stops for contacting the rim when the end cap is in the third position to  
15 prevent axial movement of the rim beyond the stops; the collar further comprising circumferential recesses between the ribs such that with the end cap in the second or third positions, the maximum air flow can pass through the circumferential recesses between the  
20 housing and the collar when a user applies suction to the mouthpiece.

6. An inhalation apparatus as claimed in claim 4, wherein the housing comprises a collar comprising the  
25 inwardly directed rim and a plurality of axial ribs on an internal surface of the collar, said rim and ribs; with the end cap in the first position, forming a close fit with the outwardly directed flange of the end cap so that there is no or a minimum air flow  
30 through the housing, an end of the axial ribs furthest from the rim comprising position stops for contacting the rim when the end cap is in the third position to prevent axial movement of the rim beyond the stops; the collar further comprising circumferential recesses  
35 between the ribs such that with the end cap in the

second or third positions, the maximum air flow can pass through the circumferential recesses between the housing and the collar when a user applies suction to the mouthpiece.

5

7. An inhalation apparatus as claimed in any preceding claim, wherein the minimum air flow is provided by a bleed hole in the housing.

10

8. An inhalation apparatus as claimed in claims 1 to 6, wherein the minimum air flow is provided by a bleed hole in the end cap.

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9. An inhalation apparatus as claimed in any preceding claim, wherein the ratio of the maximum volume flow rate of air to the minimum volume flow rate of air lies in the range 8 to 12.

20

10. An inhalation apparatus as claimed in any preceding claim, wherein the ratio of the maximum volume flow rate of air to the minimum volume flow rate of air lies is approximately 10.

25

11. An inhalation apparatus as claimed in any preceding claim, wherein the end cap is biased in use into the first position by means of the pressurised dispensing container.

30

12. An inhalation apparatus substantially as hereinbefore described with reference to and as shown in the accompanying drawing.

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ST15455/2



Application No: GB 9705388.8  
Claims searched: 1-12

Examiner: L.V.Thomas  
Date of search: 3 June 1997

**Patents Act 1977**  
**Search Report under Section 17**

**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5T (TBE)

Int Cl (Ed.6): A61M 15/00

Other: Online: WPI, CLAIMS

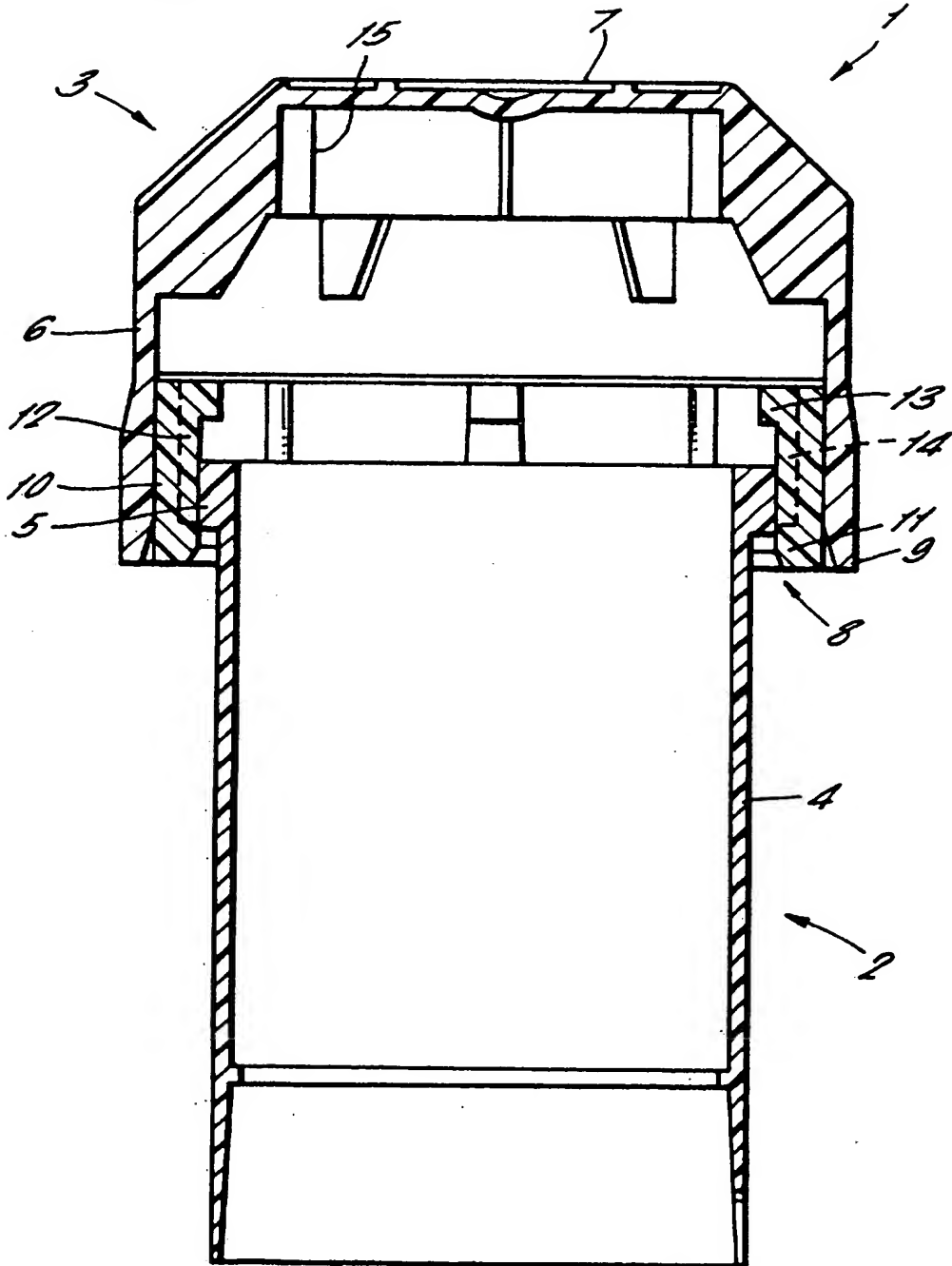
**Documents considered to be relevant:**

Category	Identity of document and relevant passage	Relevant to claims
X	GB 2061116 A (Lehti) see p.2 ll.5-23 and Figs.1 and 2	1,4
A	WO 93/09830 A1 (Pesenti et al.) see p.3 ll.10-30	1

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

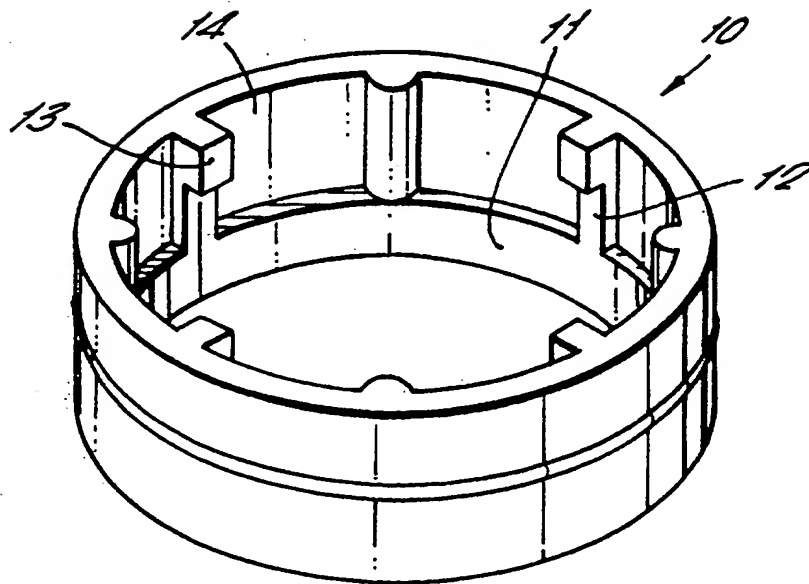
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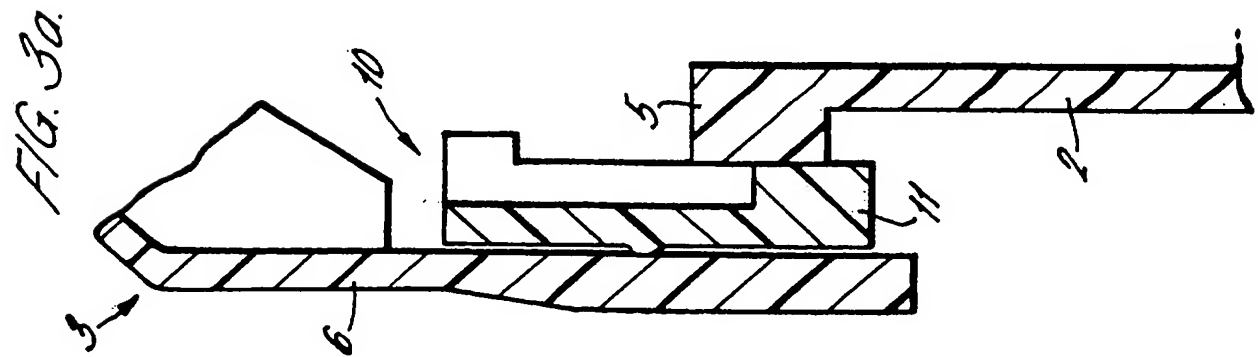
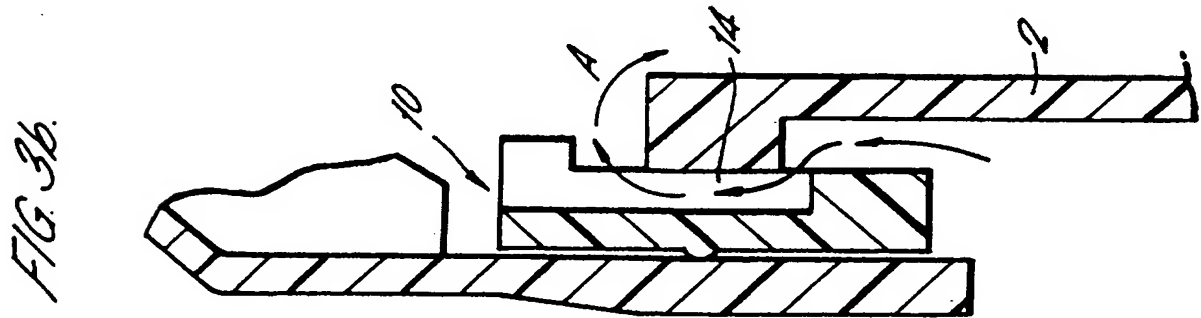
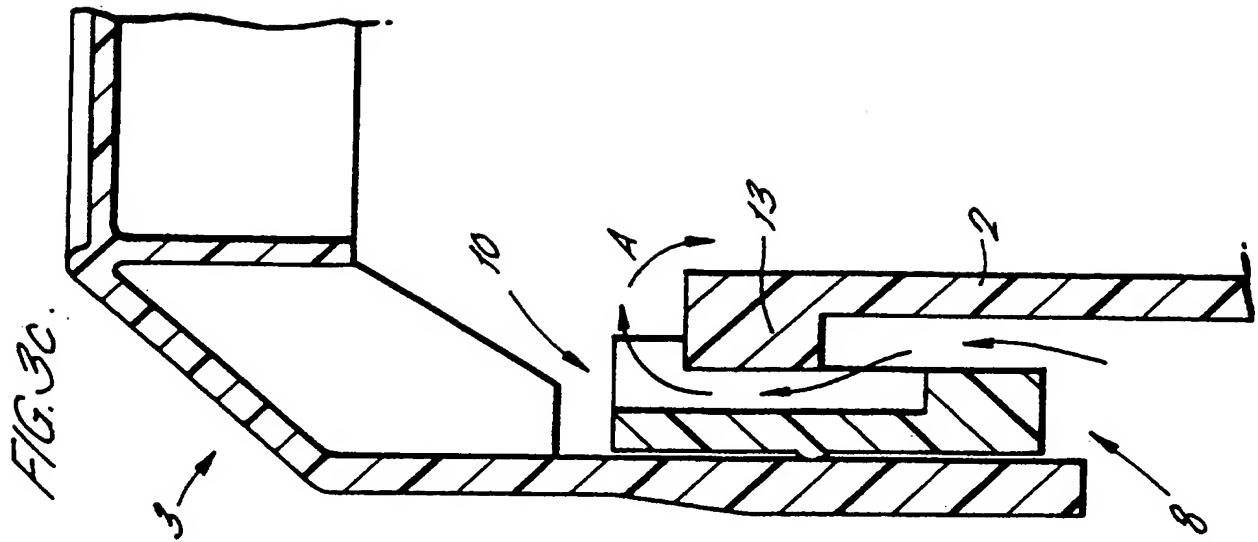
FIG. 1.



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FIG. 2.





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FIG. 4.

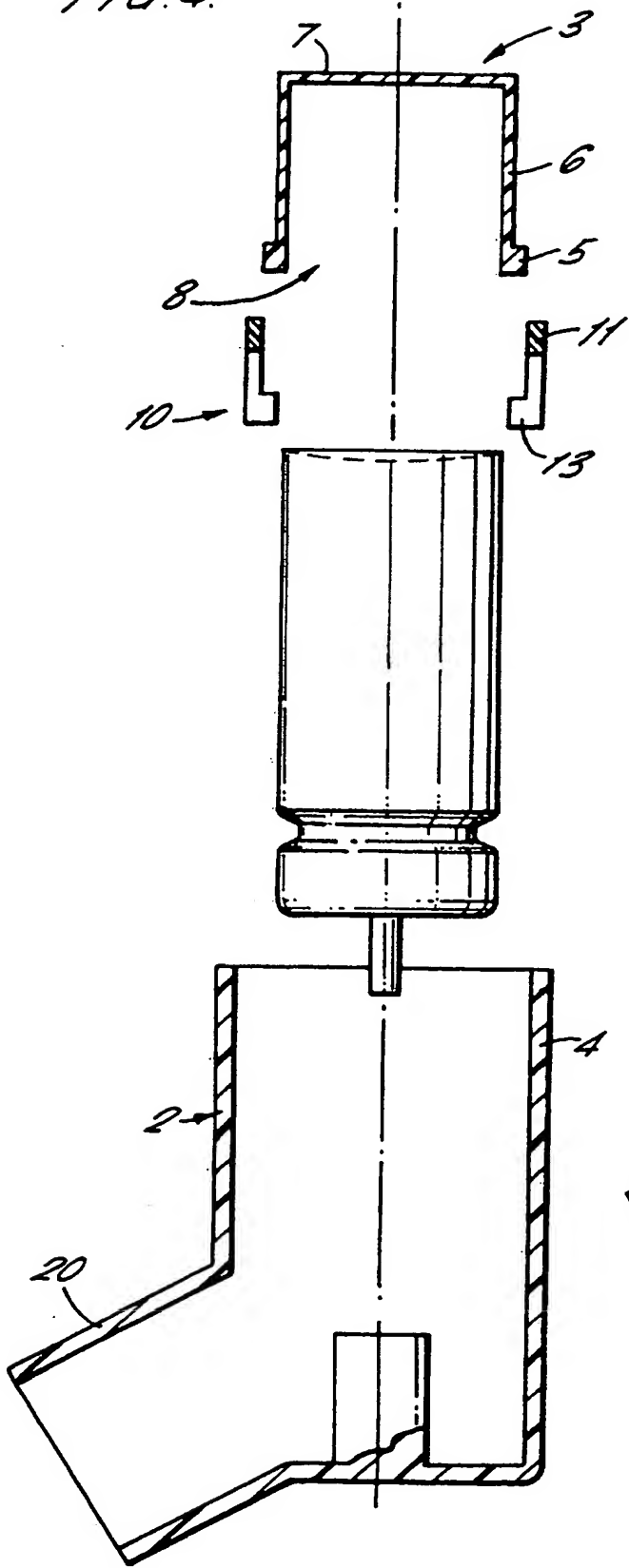


FIG. 5.

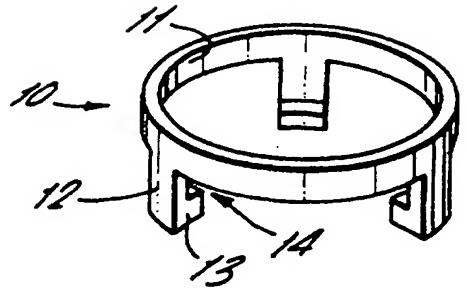


FIG. 6.

